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Ocular response to two extended wear modalities

Abstract

Purpose: To investigate the ocular reaction of two extended wear modalities by comparing ocular responses to the Ciba Night & Day vs. Acuvue 2.

Methods: Subjects wore Ciba Night & Day lenses continuously for 30 days extended wear and were monitored for hypoxia related complications. In phase two of the study, the subjects were switched to Acuvue 2 lenses on a 6 day extended wear schedule and monitored for the same criteria.

Results: The Ciba Night & Day lens showed significantly less ocular response in lirnbal injection, conjunctival staining, corneal neovascularization, conjunctival injection, and corneal staining. There was not a significant difference in the incidence of epithelia¹ microcysts between the two types of lenses.

Discussion: In this study the usage of silicone hydrogel materials reduced the extended wear ocular responses that have been problems in the past.

Degree Type

Thesis

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Committee Chair

Peter Bergenske

Subject Categories

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OCULAR RESPONSE TO TWO EXTENDED WEAR MODALITIES

BY

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A THESIS SUBMITTED TO THE FACULTY OF THE
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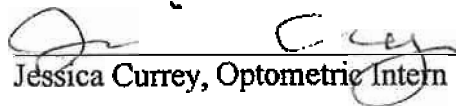
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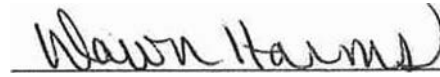
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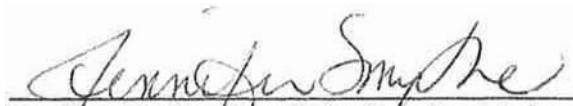


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Biographies

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1994-1998: Pacific University, undergraduate degrees awarded in Biology and Philosophy with Bioethics emphasis.

- ☞ Involvement: resident assistant, peer review board member, president and active member S.O.A.R. (student outreach admissions representative), vice-president and co-founder of the pre-med club, member and scholarship recipient of Beta-Beta-Beta National Biological Honors Society, physics teaching assistant, biology mentor, biology tutor, new student orientation, and multiple committee involvement.
- ☞ Research & Publications: conducted at Oregon Regional Primate Research Center and co-authored paper in Journal of Endocrinology.

1999-2003: Pacific University College of Optometry

- ☞ Involvement: United States Air Force Health Professions Scholarship Recipient, Class Treasurer, Admissions Representative, A.M.I.G.O.S. member and eye-care volunteer in El Salvador, American Optometric Student Association, American Academy of Optometry, yearbook committee, graduation banquet committees, graduation announcement committee, hiring committee, and multiple other committees. Part time employment at a local optometric office throughout all four years of optometry school.

DAWN L. HARMS

1996-2000: Pacific University, Bachelor of Science awarded, Major in Visual Sciences.

- ☞ Involvement: President of the Pre-Optometry Club, Member of S.O.A.R.

2000-2003: Pacific University College of Optometry

- ☞ Involvement: A.M.I.G.O.S. member, American Optometric Student Association, American Academy of Optometry, Alaska Optometric Association member, Beta Sigma Kappa International Optometric Honor Society, Oregon Optometric Association member, Yearbook Committee.
- ☞ Future Plans: Practice optometry in the Northwestern United States.

JESSICA CURREY

1992-1996: Colorado State University, Bachelor of Science awarded, Major in Biology, Minor in Human Anatomy and Physiology

- ☞ Involvement: Poudre Valley Hospital Emergency Room Volunteer, Physics Tutor

1999-2003: Pacific University College of Optometry

- ☞ Involvement: Army Health Professions Scholarship, Armed Forces Optometry Society (National Liaison), A..M.I.G.O.S. (Participated in trips to Costa Rica, Honduras, & Chile), Beta Sigma Kappa International Optometric Honor Society, American Optometric Student Association, Oregon Optometric Association.
- ☞ Future Plans: Practice optometry in the United States Army.

Abstract

Purpose: To investigate the ocular reaction of two extended wear modalities by comparing ocular responses to the Ciba Night & Day vs. Acuvue 2. **Methods:** Subjects wore Ciba Night & Day lenses continuously for 30 days extended wear and were monitored for hypoxia related complications. In phase two of the study, the subjects were switched to Acuvue 2 lenses on a 6 day extended wear schedule and monitored for the same criteria. **Results:** The Ciba Night & Day lens showed significantly less ocular response in limbal injection, conjunctival staining, corneal neovascularization, conjunctival injection, and corneal staining. There was not a significant difference in the incidence of epithelial microcysts between the two types of lenses. **Discussion:** In this study the usage of silicone hydrogel materials reduced the extended wear ocular responses that have been problems in the past.

Introduction

The advent of the silicone hydrogel material has been revolutionary in the field of contact lenses. The silicone hydrogel lenses have an oxygen transmission at approximately six times greater than conventional hydrogel lenses. These lenses are among the few lenses that meet the Holden/Mertz criteria for overnight wear of 87 barriers to not cause corneal edema past the normal amount. But, the use of these lenses as a 30 day continuous wear modality has been controversial due to the high rate of complications associated with extended wear in the past.

Extended wear of soft contact lenses was first approved by the FDA in 1979 for therapeutic use in post-cataract patients. In 1981, the first soft contact lenses were approved for cosmetic use of up to 2 weeks of extended wear. The 30-day extended wear approval was granted in 1983. Clinical trials were very promising, with an incidence of microbial keratitis of only 0.2%. Extended wear continued to become very popular in the 1980's, with up to 30% of the population using this type of modality.

The questions about the safety of extended wear were soon to arise. Many reports of infectious keratitis began to appear within several years of FDA approval for extended wear. Schein, Glynn, et al. published a study in the New England Journal of Medicine in 1989 that compared the risk of ulcerative keratitis among the users of daily and extended wear soft contact lenses. The results of this study showed a 10 to 15 times greater risk of ulcerative keratitis in extended wear use of soft contact lenses. Immediately following this study, the FDA rescinded its approval for 30 day extended wear and moved it back to seven days. Practitioners became extremely reluctant to recommend extended wear to their patients.

Since that time, extended wear has been closely examined, with close attention being paid to complications associated with extended wear. Ulcerative keratitis is the complication that is investigated most frequently due to the risk of reduction of best corrected visual acuity and impact on long term vision. Although ulcerative keratitis often gets the most attention, numerous other complications are reported from extended wear of contact lenses. These include infiltrative keratitis, superficial punctate keratitis, corneal edema, microcysts, neovascularization, papillary conjunctivitis, changes in endothelial cell morphology, and conjunctival hyperemia. With this long list of complications, several mechanisms have been postulated for these changes in corneal physiology.

The first, and possibly most significant, mechanism of extended wear complications is hypoxia. It has been shown that contact lens hypoxia alters the glycocalyx layer of the corneal epithelium, exposing more corneal receptor sites for *Pseudomonas* adherence. This creates a greater risk for infection. Additionally, hypoxia has been correlated with a reduction in the surface cell shedding, or desquamation rate. This indicates that the natural life cycle of the epithelial cell is slowed, altering corneal physiology. Hypoxia has been implicated as one the major reasons for complications in extended wear, but it is not the only explanation for corneal changes.

An additional mechanism that has been investigated for extended wear complications is changes occurring in the closed eye environment. A whole cascade of inflammatory reactions occurs in the closed eye environment. The introduction of a contact lens to this delicate balance complicates the situation even further. While the eye is closed, without the presence of a contact lens, inflammatory elements are present in increased concentrations and mediators of inflammation are activated. The mechanism for this cascade of immune reactions is uncertain, but this activation of the immune system would indicate that the closed eye environment creates favorable environment for infection.

One other mechanism that has been associated with complications is the stagnation of tear film under the contact lens. Normal tear film circulation allows for removal of debris and bacterial organisms from the corneal surface, as well as mobility of the immune mechanisms needed to adequately protect the cornea. Reduction of tear exchange beneath contact lenses can provide a greater period of time for bacterial organisms to invade and infect the cornea. Debris entrapment has also been associated with increased rates of infiltrative keratitis.

The last mechanism associated with extended wear complications is contact lens deposits. Surface deposits on lenses have been associated with papillary conjunctivitis and infiltrative keratitis. Lens deposits have not been as much of a concern since the frequent replacement of contact lenses has become more popular. But, with the extended wear of lenses over a longer period of time without removal could lead to more complications related to lens deposits.

With all of the knowledge that has been acquired in the last 20 years in the area of extended wear of lenses, it is still not clear if the continuous wear modality will be worth the risk of known complications from poorly understood mechanisms for these complications. The silicone hydrogel lenses have answered one of the major concerns in the relief of hypoxia with this hyper Dk material. Hopefully elimination of hypoxia will prove to be the answer to the complication question and the continuous wear modality will become something that all practitioners are comfortable recommending for their patients.

This study investigated the ocular response in the form complication rates of two extended wear modalities. The two modalities investigated were 30 day continuous wear of Ciba's Focus Night & Day lens and seven day, six night extended wear of Acuvue 2 lens.

Material and Methods

Study Objectives

The goal of this study was to investigate the ocular response of wearing Focus Night and Day lenses continuously for 30 days. These findings were compared to Acuvue 2 lenses worn on a 6 day extended wear schedule.

Study Design

Thirty subjects, primarily optometry students, were selected to complete a two month, two phase study. The subjects were assigned to wear either the Focus Night and Day lenses or Acuvue 2 lenses. The Focus Night and Day lenses were worn continuously for 30 days. Subjects were instructed to record any instance in which the lenses were removed and the reason for removal. The subject also documented the number of times artificial tears were used per day.

In the second phase of the study, the subjects were switched to Acuvue 2 lenses worn on a seven day, six night extended wear schedule. There was no washout period between the two phases of lens wear. The lenses were removed on the seventh day, and the subject slept without lenses that night. The lenses were cleaned with Quick Care and stored overnight. The same lenses were then inserted the next morning and worn again for week. This regimen was continued for one month. The same protocol was followed for tracking removal of lenses and use of artificial tears.

The most crucial part of this study was careful evaluation and monitoring of the cornea for any changes secondary to hypoxia. The ocular responses monitored were:

1. conjunctival injection
2. limbal injection
3. corneal neovascularization
4. corneal infiltrates
5. epithelial microcysts
6. corneal edema
7. corneal staining
8. conjunctival staining

The intervals for follow-up were as follows: dispensing visit, one day, two weeks, and four weeks for phase one and phase two of the study. We used the data collected at the four week visit for statistical analysis.

Study Materials

Focus Night & Day (Ciba)

FDA Group

Material

Oxygen Permeability (Dk)

Oxygen Transmissibility (Dk/t)

Water Content

Center Thickness at -3.00

Base Curve

Power

Diameter

Surface Treatment

Group I

Lotrafilcon A fluorosilicone hydrogel

140 barrers

175 barrers/cm

24%

0.08

8.4, 8.6 mm

+6.00 to -10.00

13.8 mm

yes

Acuvue 2 (Vistakon)

FDA Group

Material

Oxygen Permeability (Dk)

Oxygen Transmissibility (Dk/t)

Water Content

Center Thickness at -3.00

Base Curve

Power

Diameter

Surface Treatment

Group II

Etafilcon A

28 barrers

35 barrers/cm

58 %

0.08

8.3, 8.7 mm

+8.00 to -12.00

14.0 mm

no

Inclusion Criteria

- 1) The subject must have been at least 18 years of age.
- 2) Must have been free of any anterior segment disease that contraindicated extended wear.
- 3) Must have had a best corrected visual acuity of 20/25 in each eye.
- 4) Must have had a spherical distance refraction of 20/30 in each eye.
- 5) Must have read and signed the informed consent document.
- 6) Must have agreed to wear the lenses on an extended wear basis.

Exclusion Criteria

- 1) Any lid or anterior segment disease which contraindicated extended wear.
- 2) Systemic disease which affected ocular health, e.g., Graves disease, diabetes, Sjogren's syndrome.
- 3) Corneal abnormalities, which included corneal scars, corneal infiltrates, corneal staining, corneal edema, corneal neovascularization, and epithelial microcysts.
- 4) Refractive astigmatism greater than 1.50 D.
- 5) Pregnancy

Experimental Design

1) Baseline Evaluation

All subjects were required to have a complete vision examination at a Pacific University College of Optometry Clinic.

Subjects were screened at the baseline evaluation to determine eligibility. All participants were required to sign two copies of the informed consent document and kept one copy of the consent form. The following procedures were performed:

Case history, including habitual contact lens wear and solutions
Habitual visual acuity
Topography
Measurement of horizontal visible iris diameter
Slit lamp examination with white light
Conjunctival and corneal staining evaluation with fluorescein

If any corneal findings were present, grading was performed using the grading scales in Appendix 1. If the subject was determined to be a candidate for the study, a diagnostic fitting of either the Focus Night & Day lenses or Acuvue 2 lenses was performed. When an adequate fit was achieved, the lenses were dispensed and the following instructions were given.

For those subjects fit in the Night & Day lenses, they were instructed to wear the lenses continuously for 30 days. The subjects were told to remove the lenses when only absolutely necessary. If the lenses were removed, they were to be cleaned with Quick Care starting solution and then rinsed with finishing solution and reinserted. A log sheet was given to each subject to record the number of times the lenses were removed and for what reason. Artificial tears were given to the subjects to be used only when absolutely necessary. The number of times artificial tears were used per day was also recorded on the log sheet.

For the subjects fit in the Acuvue 2 lenses, they were instructed to wear the lenses on a seven day, six night extended wear schedule. On the seventh day, the lenses were removed, cleaned with Quick Care solution and stored overnight. The lenses were then inserted the next morning and worn for another seven day, six night schedule. The same protocol was used the logging the number of lens removals and use of artificial tears.

2) Follow-up visits: One day, two weeks, and four weeks

A similar protocol was used for each follow-up visit. A history was taken, which included questions regarding subjective evaluation of comfort and dryness. The log sheet was evaluated to monitor lens removal and artificial tear use. A detailed slit lamp examination was performed to evaluate the lenses and cornea. Grading the ocular response was performed using the grading scales 0-4 (see Appendix 1). The lenses were then removed to perform fluorescein evaluation. The fluorescein was then rinsed from the eye and the lenses were reinserted.

3) Phase 2: Lens Crossover

At the end of one month, the subjects were switched from the lenses they were wearing to the other lens modality. All protocol from here was similar, including wearing schedules, follow-up visits at one day, two weeks, and four weeks and use of the log sheets. The subjects' participation was concluded following one month of wear in the alternate lens modality.

Results

Statistical differences were found (using two way ANOVA repeated measures) between ocular responses to the Night & Day and Acuvue 2 contact lenses at the one-month follow-up visit. The Night & Day lens had significantly less ocular response than the Acuvue 2 lens in five of the eight ocular response categories monitored. All statistical analysis was done comparing the ocular response at approximately 30 days. Figures 1, 2, & 3 display the actual number of subjects exhibiting the ocular responses monitored and at what grade. Figure 4 displays the Mean Ocular Response and the statistical t values and p values.

The five ocular responses monitored in which the Night & Day lens that had significantly less ocular response were (listed most statistically significant to least): limbal injection ($t = 4.39$, $p < .001$), conjunctival staining ($t = 2.87$, $p = 0.003$), corneal neovascularization ($t = 2.76$, $p = 0.004$), conjunctival injection ($t = 2.35$, $p = 0.012$), and corneal staining ($t = 2.33$, $p = 0.013$). There was not a statically significant difference in epithelial microcysts ($t = -0.026$, $p > 0.5$) between the two types of lenses. Two of the ocular responses monitored (corneal infiltrates and corneal edema) were not found during the Night & Day phase or the Acuvue 2 phase, and are not displayed graphically in the Figures.

Figure 5 is a table of the two way repeated measures ANOVA statistical analysis. The table shows that there was indeed a significant difference in ocular response between the two lens types ($F = 32.43$, $p > .001$). This analysis also showed that there was a significant difference between the ocular response categories as well.

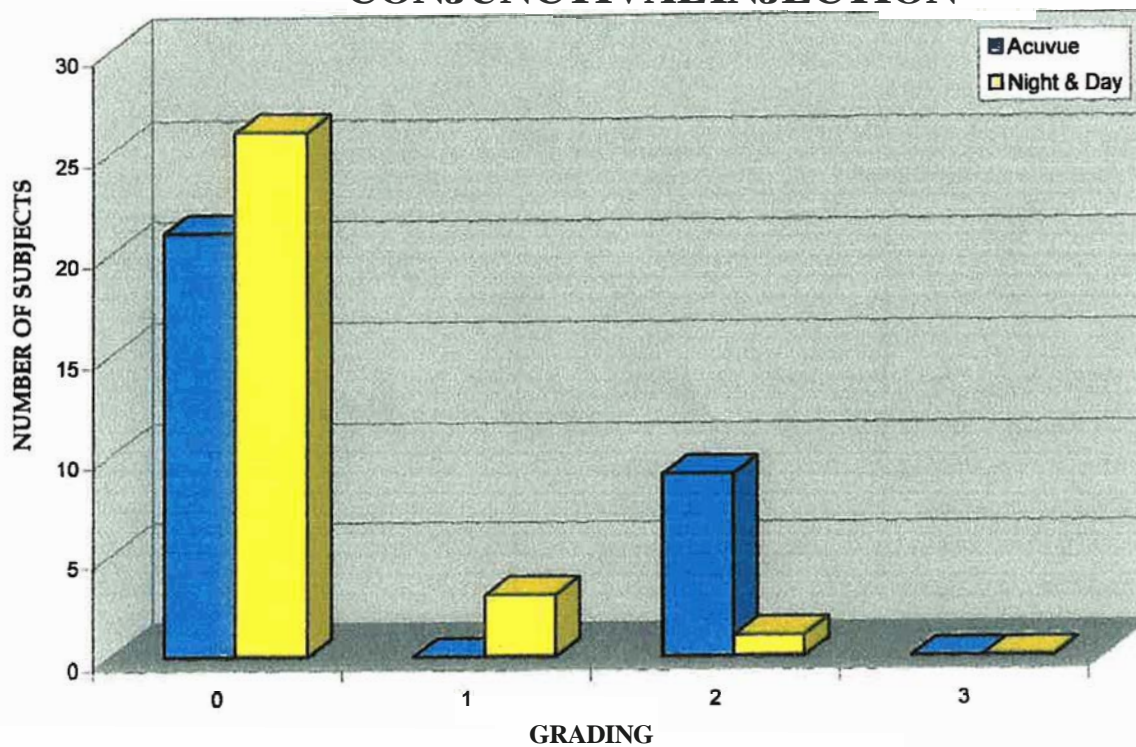
Discussion

The overnight wear of disposable hydrogels produced complications in the mid-to-late 1980's primarily due to hypoxic stresses placed on the ocular tissues. The introduction of the silicone hydrogels, with improved oxygen transfer through the lens to the eye, was a breakthrough in the arena of contact lenses. Based on this study we conclude that extended wear of the higher Dk Ciba Night & Day lens has significantly less ocular responses than extended wear of the Acuvue 2. This indicates that the usage of silicone hydrogel materials may reduce many of the extended wear ocular responses that were problems in the past.

In our study we collected data regarding comfort, usage of artificial tears, and frequency of removal of the contact lenses. This data however was not statistically analyzed and therefore not discussed in the results or discussion. This data may be analyzed at a later date.

To provide the highest quality of care to patients it is essential for the eye care community to understand the factors that may be causing some of the untoward ocular responses we have seen in the past with extended wear contact lenses. Continued research in the area of silicone hydrogel lenses is necessary to continue enhancing our knowledge of these exciting materials.

CONJUNCTIVAL INJECTION



LIMBAL INJECTION

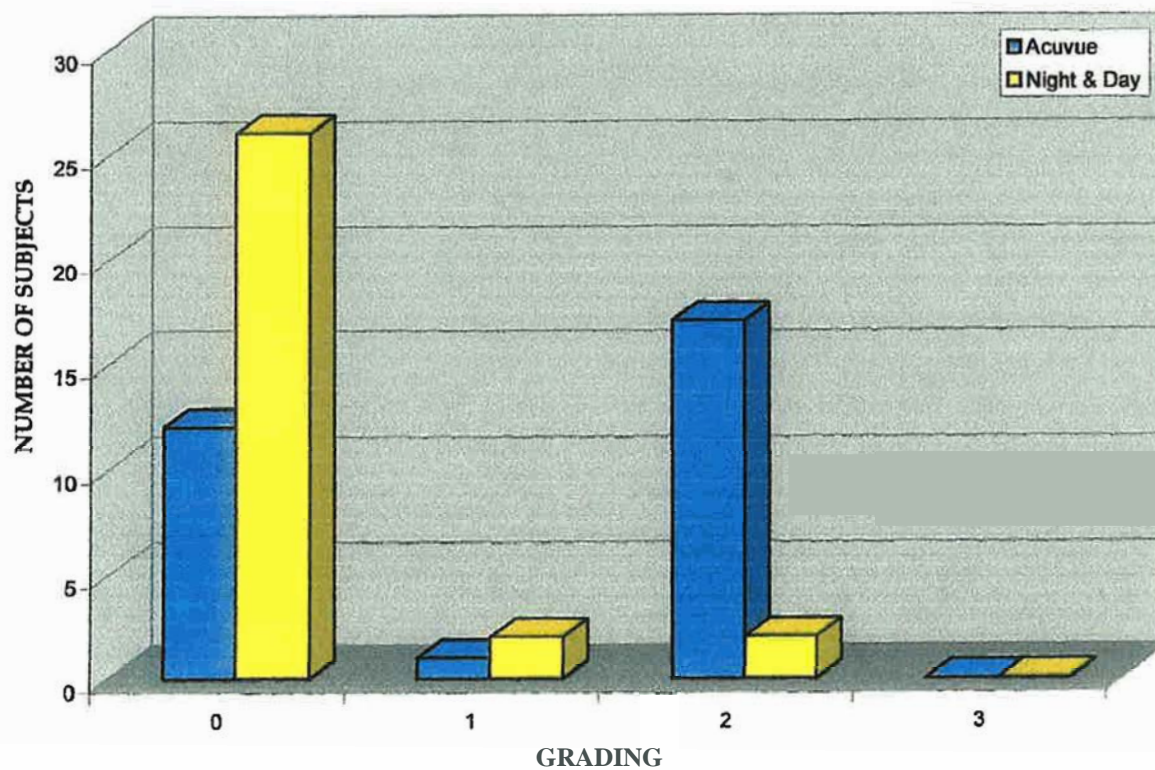
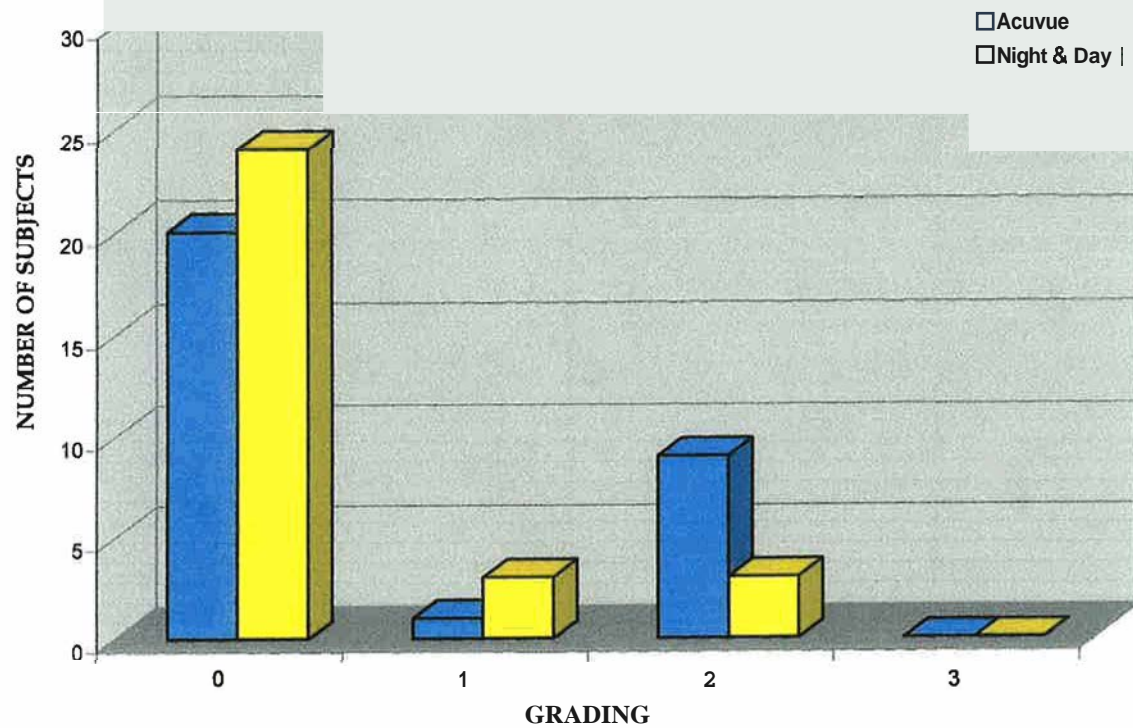


Figure 1.

CORNEAL NEOVASCULARIZATION



EPITHELIAL MICROCYSTS

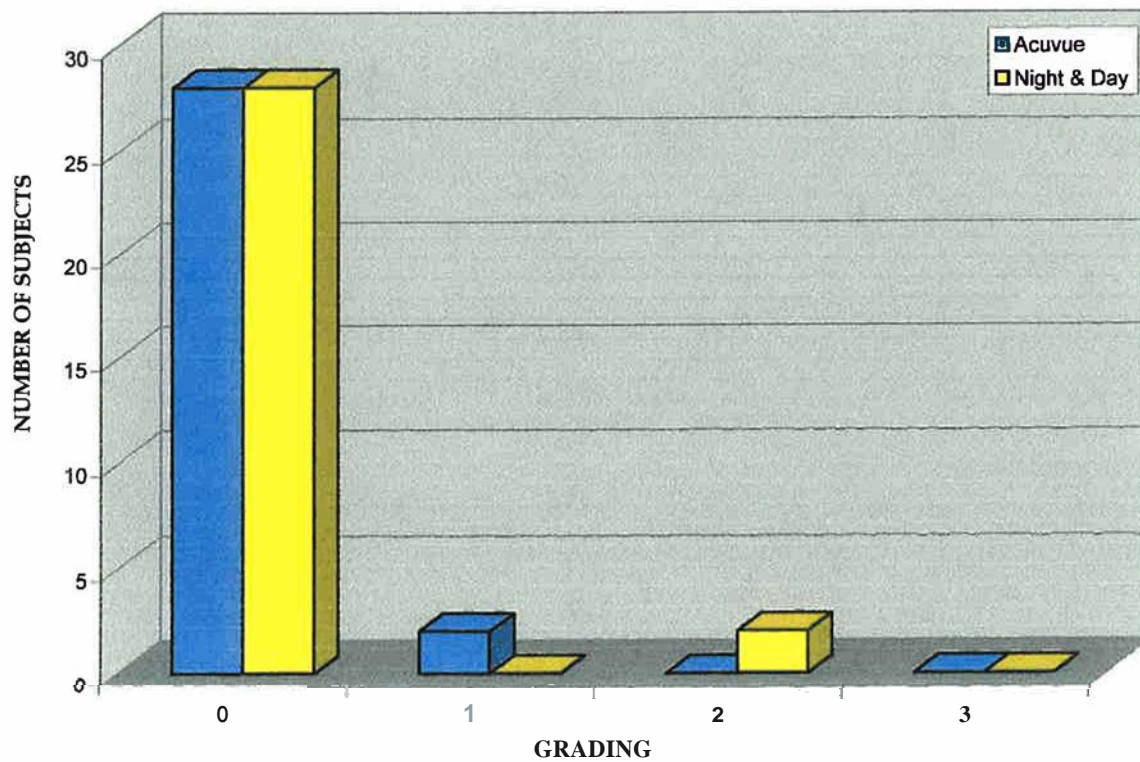


Figure 2.

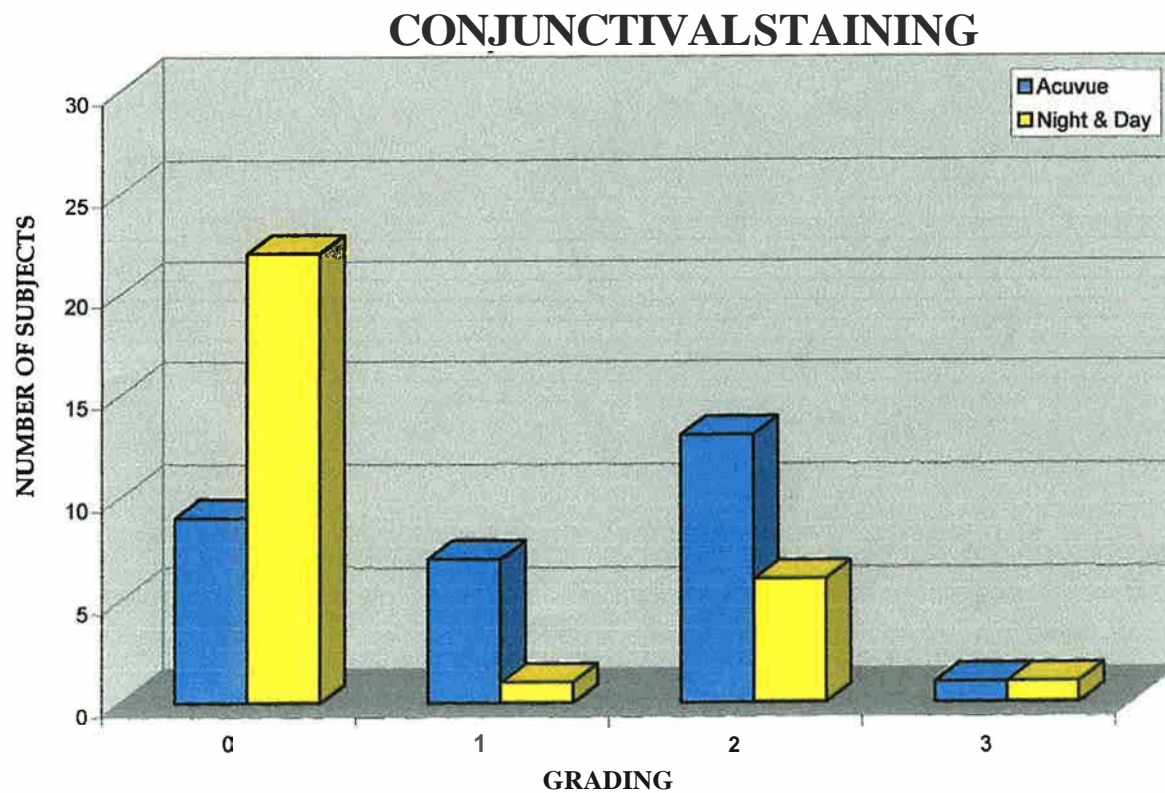
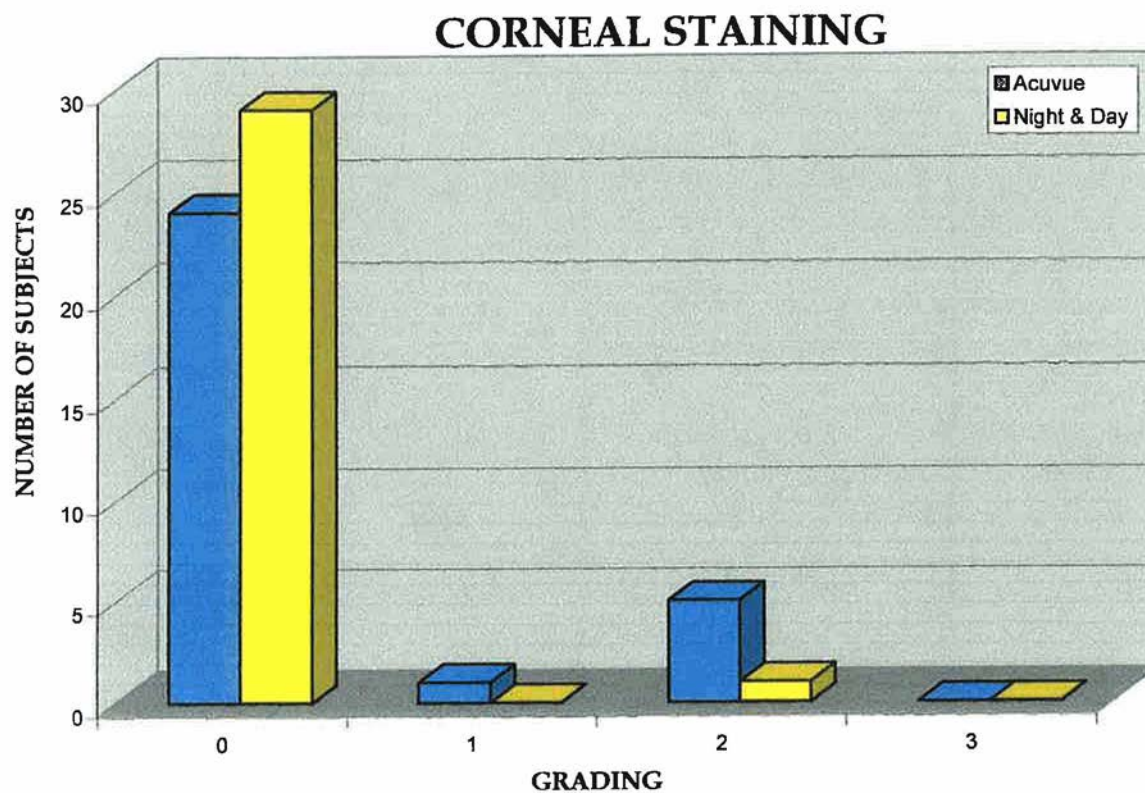
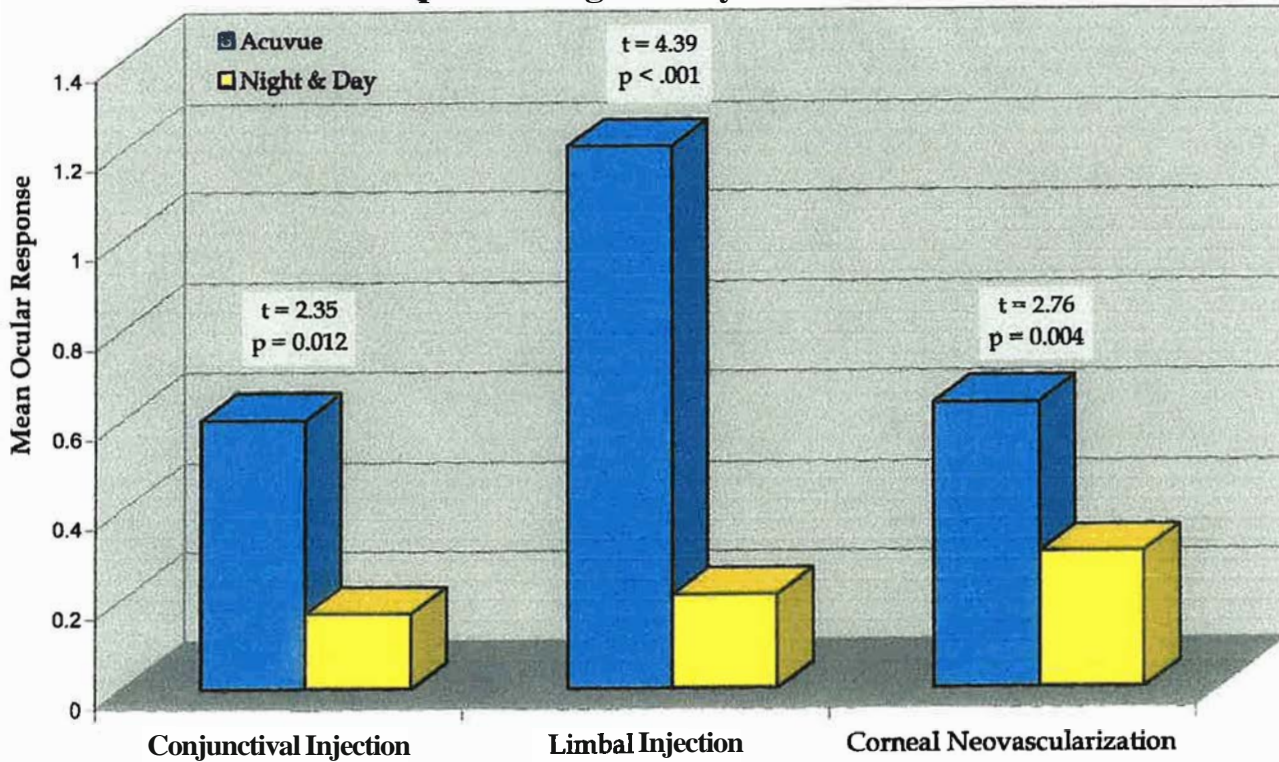


Figure 3.

Ocular Response of Night & Day vs Acuvue Extended Wear Lenses



Ocular Response of Night & Day vs Acuvue Extended Wear Lenses

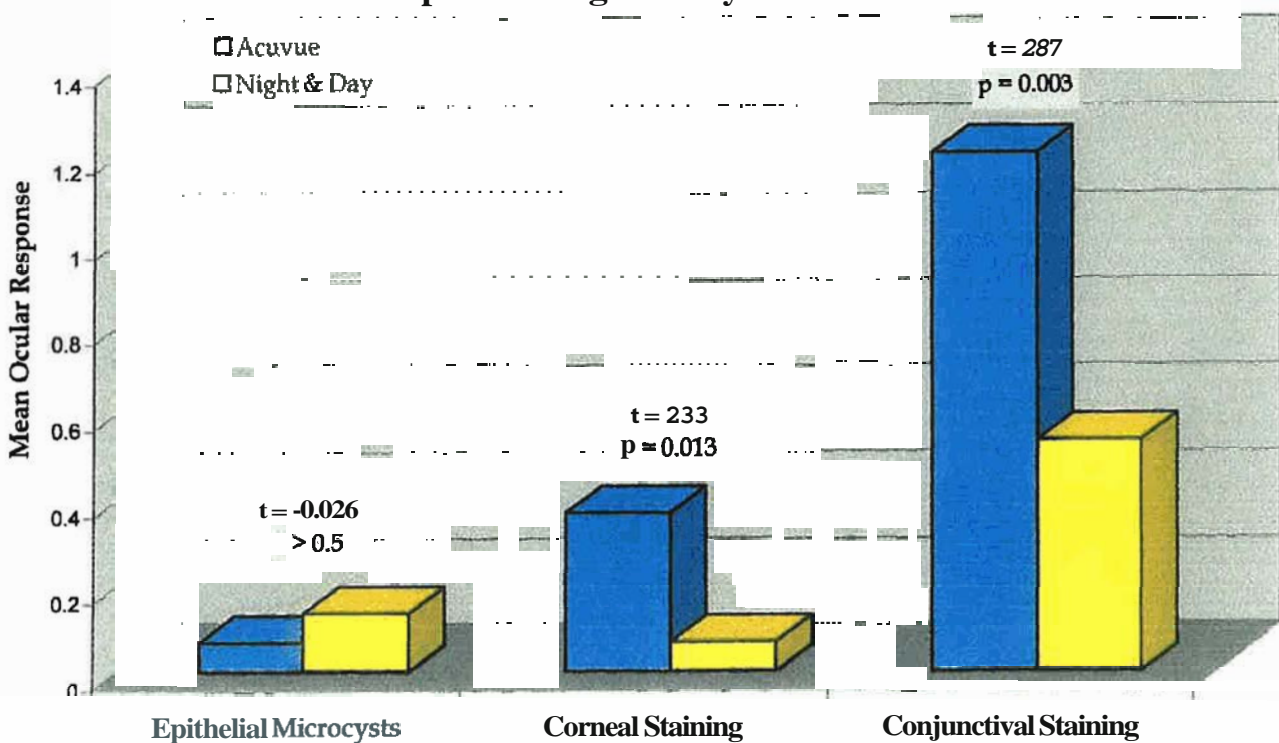


Figure 4.

ANOVA

<i>Source of Variation</i>	SS	<i>df</i>	<i>MS</i>	F	<i>P-value</i>	<i>rit</i>
OCULAR RESPONSE CATEGORY	35.12381	6	5.853968	12.77573	3.14E-13	2.120913
LENS TYPE	14.85952	1	14.85952	32.42949	2.37E-08	3.864471
Interaction	11.72381	6	1.953968	4.264349	0,000351	2.120913
Within	186.0333	406	0.45821			
Total	247.7405	419				

Figure 5.

Grading Scales

Coniunctival Iniection

0 None

- 1 Very slight hyperemia of conjunctival vessels in one quadrant.
- 2 Slight hyperemia of conjunctival vessels in more than one quadrant.
- 3 Moderate hyperemia of conjunctival vessels in any quadrant.
- 4 Severe hyperemia of conjunctival vessels in all quadrants.

Limbal Injection

0 None

- 1 Very slight hyperemia of limbal vessels in one quadrant.
- 2 Slight hyperemia of limbal vessels in more than one quadrant.
- 3 Moderate hyperemia of limbal vessels in any quadrant.
- 4 Severe hyperemia of limbal vessels in all quadrants.

Corneal Neovascularization

0 None

- 1 Slight vascularization less than 1.5 mm into the cornea in one quadrant.
- 2 Mild vascularization less than 1.5 mm into the cornea in more than one quadrant.
- 3 Moderate vascularization 1.5 mm to less than 2.5 mm into the cornea in any quadrant.
- 4 Severe vascularization greater than 2.5 mm into the cornea in any quadrant.

Epithelial Microcysts

0 None

- 1 Slight with fewer than 10 microcysts.
- 2 Mild with 10 to 20 microcysts.
- 3 Moderate with 20 to 50 microcysts.
- 4 Severe with greater than 50 microcysts.

Corneal Edema

0 None

- 1 Slight with barely discernable haziness.
- 2 Mild with definite focal or generalized haziness.
- 3 Moderate with significant localized or generalized haziness.
- 4 Severe with definite, generalized haziness.

Corneal Staining

0 None

- 1 Slight with minimal superficial staining in any area.
- 2 Mild with lightly coalescent or diffuse punctate staining in more than one quadrant.
- 3 Moderate with significant or densely coalesced staining in more than one quadrant.
- 4 Severe with significant or densely coalesced staining in all quadrants.

Coniunctival Staining

0 None

- 1 Slight with minimal staining in any area. —
- 2 Mild with diffuse staining in more than one quadrant.
- 3 Moderate with diffuse staining in more than two quadrants.
- 4 Severe with diffuse staining in all quadrants.

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Acknowledgments

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